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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,770	12/04/2000	Znenya Li	CL000651	5477

25748 7590 02/24/2003

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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	12

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/727,770	LI ET AL.	
	Examiner	Art Unit	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 24-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2000* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This is a First Office Action on the Merits of the application filed 4 December 2000 claiming benefit of U.S. Provisional application 60/208,836 filed 2 June 2000. This Office Action is a response to the "Preliminary Amendment" filed 27 November 2002 (Paper No. 11). Claims 1-3, 5-7 and 10-23 were canceled, claims 4 and 8 were amended and claims 24-29 were added in Paper No. 11. Claims 4, 8, 9 and 24-29 are pending and under consideration in the application.

Election/Restrictions

Applicant's election without traverse of Group III, directed to nucleic acid molecules, vectors, host cells and methods of using, in Paper No. 11 is acknowledged.

Drawings

The drawings are objected to for the reasons indicated on the attached PTO-948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front

of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Specification

The disclosure is objected to because of the following informalities: The figures contain sequence not identified by SEQ ID NO. The "Brief Description of the Drawings" should be amended to include sequence identifier numbers for the disclosed sequences.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4, 8, 9 and 24-29 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well-established utility.

The claims are directed to an isolated nucleic acid molecule consisting of the sequence set forth as SEQ ID NO:1 and 3, and a nucleic acid molecule encoding a polypeptide comprising the amino acid sequence set forth as SEQ ID NO:2. Beginning on page 44, the specification teaches a variety of uses for the claimed nucleic acid molecules, including: probing for related nucleic acids; probing to determine chromosomal position; probing to determine expression levels; PCR amplification of portions of the nucleic acid molecule; constructing recombinant vectors including expression vectors; expression of the encoded protein or antigenic portions thereof for the purpose of protein purification, drug screening or to raise antibodies; diagnostic assays; and treatment. However, applying each of these utilities to a real-world problem requires that the function of the nucleic acid molecule is known. For example, probing for related nucleic acid molecules or expression levels is not useful unless some functional meaning can be attributed to the relatedness or expression of the identified nucleic acid molecules; expressing a protein that has no known function has no specific utility other than to determine what that protein does; results from a diagnostic assay are not useful if the findings cannot be correlated with a pathological state; and a method of treatment is not useful without knowing what patient population can be treated according to the method. In the instant case, the asserted function of the claimed nucleic acids is to encode a vacuolar ATP synthase 16 kDa proteolipid subunit. This function is based on the structural similarity of the protein encoded by the claimed nucleic acid molecule (SEQ ID NO:2) with known vacuolar ATP synthase 16 kDa proteolipid subunits. However, the asserted function is not credible because, although the disclosed polypeptide is

more similar to vacuolar ATP synthases than other proteins, the degree of similarity is well outside of the similarity found within the family of proteins having the asserted function.

The instant SEQ ID NO:2 is most similar to the human ATP synthase 16 kDa proteolipid subunit (gi| 4502313), having 71% identity with 9% gaps over 153 of 205 amino acids (see Figure 2). In contrast, gi| 4502313 has 97% identity with 0% gaps with gi| 2599050 (ovine ATP synthase 16 kDa proteolipid subunit), 96% identity with 0% gaps with gi| 137477 (bovine ATP synthase 16 kDa proteolipid subunit), 90% identity with 0% gaps with gi| 109937 (mouse ATP synthase 16 kDa proteolipid subunit), and 81% identity with 1% gaps with gi| 8812 (*D. melanogaster* ATP synthase 16 kDa proteolipid subunit). This shows that proteins having the function of a ATP synthase 16 kDa proteolipid subunit are highly conserved among mammals, and that even the insect ATP synthase 16 kDa proteolipid subunit is more closely related to the human ATP synthase 16 kDa proteolipid subunit than the instant polypeptide.

Generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick *et al.* (2000) *Trends Biotechnol.* 18:34-39 teach that knowing the protein structure by itself is insufficient to annotate a number of functional classes, and is also insufficient for annotating specific details of protein function (see Box 2, page 36). Similarly, Bork (2000) *Genome Res.* 10:398-400 teaches that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially page 399). Smith *et al.* (1997) *Nature Biotechnol.* 15:1222-1223 teaches, "[t]ypical database searching methods are valuable for finding evolutionarily related proteins, but if there are only about 1000 major superfamilies in

nature, then most homologs must have different molecular and cellular functions" (second column on page 132). These teaching demonstrate the unpredictability of assigning protein function based on structure alone. Given this unpredictability and the low degree of sequence homology of the instant SEQ ID NO:2 to ATP synthase 16 kDa proteolipid subunits relative to the homology found among ATP synthase 16 kDa proteolipid subunits, the skilled artisan would not predict that the instant SEQ ID NO:2 would have the function of an ATP synthase 16 kDa proteolipid subunit. In the absence of a credible function for the claimed nucleic acid, the claimed invention lacks a credible utility.

Claims 4, 8, 9 and 24-29 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
February 12, 2003

JAMES KETTER
PRIMARY EXAMINER